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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,781	09/15/2003	Philip L. Fuchs	P27-053	1498

7590 05/03/2006

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EXAMINER

PERLINGER, SARAH E

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/662,781

Applicant(s)

FUCHS ET AL.

Examiner

Sarah E. Perlinger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 08/15/03 2-23-06 / 2-27-06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1-11 are pending.

2. ***Election/Restrictions***

Applicant's election with traverse of Group II (claims 1-9, drawn to seven-membered carbon termini-differentiated polypropionate stereopentads) in the reply filed on February 27, 2006 is acknowledged. The traversal is on the grounds that searching both groups I and II does not place such a serious burden on the Examiner because the originally filed claims 1-9 of groups I and II are sufficiently narrow to allow the Examiner to determine patentability without being subjected to serious burden. This is not found persuasive because should applicant traverse on the ground that the groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. In the instant case, then, there could have been no patentability of all the claims were restriction not made because there is anticipation for Group I. Hentemann et al. anticipated the six-membered rings of Group I (see Hentemann et al., *Org. Lett.*, 1999, 1(3), page 356, Table 2, compound 9 wherein X is hydrogen). The reference, which qualifies as a 102(b) reference, anticipates the six-membered compounds when R<sup>2</sup> is hydrogen and when R<sup>1</sup> is a methyl group.

An oversight was observed in the original restriction of record, in that the restriction requirement did not encompass all of the compounds of claim 3. Subsequently, three additional groups needed to be delineated to encompass all the subject matter of the claims.

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Group V: Claim 3, drawn to a seven-membered **bicyclic** carbon termini-differentiated polypropionate stereotetrads and stereopentads, classified in various classes and subclasses depending on species election.

Group VI: Claim 3, drawn to an aliphatic compound, classified in various classes and subclasses depending on species election.

Group VII: Claim 3, drawn to any seven-membered carbon termini-differentiated polypropionate stereotetrads and stereopentads which do not read on the base claim, claim 1, classified in various classes and subclasses depending on species election.

Correction of the restriction requirement record is hereby made.

The requirement with regard to groups I-IV is still deemed proper and is therefore made FINAL.

3. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are the absolute configurations of the substituents (for example the R<sup>1</sup>, OR<sup>2</sup> and epoxide rings) of the seven-membered ring structures. The “;” notation, in addition to the dashed and wedged lines are not sufficient to illustrate to one having ordinary skill in the art, the absolute stereochemistry of the instant claimed compounds. Notation of either R or S at each individual substituent on the ring should be used to denote the stereopositions of these substituents.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification lacks written description where a “pharmaceutically acceptable salt, solvate and polymorphs thereof” are claimed. A survey of the specification revealed no description of a salt, solvate or polymorph of the instant claimed compounds nor did it mention the chemical forms (see Specification, pages 5-8). The instant elected inventions are useful as intermediates/starting materials. No description was found that salts, solvates, or polymorphs would have the same utility absent of explicit description.

5. Claims 1-2, 4-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the instant claimed compounds(see Specification, pages 43-95), does not reasonably provide enablement for making the “pharmaceutically acceptable salts, solvates, and polymorphs thereof”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

#### Nature of Invention

The instant claims are drawn to seven-membered carbon-termini compounds, pharmaceutically acceptable salts, solvates and polymorphs thereof. The instant claimed compounds are utilized in syntheses of natural products.

#### The State of the art and Predictability

Unlike the mechanical art, the high degree of unpredictability is well recognized in the chemical synthetic art. A change in the structure of the compound may drastically affect the rate of the chemical reaction. Furthermore, a high degree of unpredictability in the art exists in utilizing polymorphs as the various polymorphs of a substance can exhibit a variety of different physical properties, which arise from differences in their molecular packing (see Brittain, *Polymorphism in Pharmaceutical Solids*, 1999, pages 5-8).

The amount of guidance and working examples

Examples 1-51 (Specification, pages 43-70) are limited to teaching one of ordinary skill how to make the compounds of the instant claims. However, these examples do not guide one of ordinary skill in the art in making the pharmaceutically acceptable salts, solvates, or polymorphs, thereof. In addition, no evidence has been provided that the pharmaceutically acceptable salts, solvates, or polymorphs thereof would have any utility in the syntheses of natural products, or that stable polymorphs or solvates exist for any of the instant claimed compounds. The salts, solvates and polymorphs thereof would not necessarily have the same chemical activity as the instant claimed compound and therefore, it is unclear whether or not they could be utilized in the syntheses of natural products.

Since insufficient teaching and guidance are provided by the specification (pages 43-70), one of ordinary skill in the art, even with a high degree of skill, would not be able to make the pharmaceutically acceptable salts, solvates, or polymorphs without undue experimentation. Polymorphs cannot be obtained without a description of how to make them.

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6.

**Allowable Subject Matter**

Claim 3 seven-carbon termini-differentiated compound as it reads on the base claim, claim 1 is allowable. Claims 1 and 3, being drawn to the elected invention, would be allowable when being incorporated into independent form, free from non-elected subject matter.

The closest art to the instant claimed seven-carbon termini-differentiated compounds is found in the following references:

Arjona et al., *J. Org. Chem.*, 1994, 59(14), pages 3909-3910.

Hentemann et al., *Tetrahedron Letters*, 38(32), page 5617.

Wanlong et al., *Org. Lett.*, 2000, 2(15), 2181-2184.

Chen et al., *Tetrahedron Letters*, 2000, 41, 7795-7799.

7.

**Conclusion**

Claim 3 as it reads on claim 1 and is drawn to a seven-carbon termini-differentiated compound is allowable.

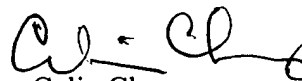
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Sarah E. Perlinger, whose telephone number is (571) 272-5574. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang, can be reached at (571) 272-0562. The fax number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



04/24/2006



Celia Chang  
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Art Unit 1625